

REMARKS**I. Status of the Claims**

Claims 1 to 7 and 10 are pending in the above-referenced application.

Claim 2 has been amended by excluding gout and cerebrovascular convulsion from the listed leukotriene-related diseases. Further, Claims 8 and 9 have been deleted. No new matter has been entered.

As explained below, claim 10 was not examined in the Office Action. However, it is believed that claim 10 should have been examined, and therefore, it will be assumed that claim 10 is one of the examined claims here.

II. Summary of Interview with Examiner

Applicants are grateful for the Examiner's time on October 6, 2006 to discuss the above-referenced application. During the interview, Applicants requested clarification on claim 10 which was not examined in the Office Action. Applicants assumed that claim 10 was one of the examined claims because it is directed to the elected species. The Examiner agreed with the Applicants and apologized for the inadvertent oversight regarding claim 10.

III. Claim Rejections under 35 U.S.C. §112

The Examiner has rejected claims 1 – 7 and 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner elaborates on her rejection as to how this requirement can be satisfied, such as chemical formulae or drawings. In addition, the Examiner, at page 5 of the Office Action, indicates that the specification has not provided any working examples directed to administration of the inventive benzoxazole compounds for inhibiting 5-lipoxygenase thereby preventing or treating diverse leukotriene-related diseases.

In this regard, Applicants respectfully traverse the Examiner's rejection, and refer the Examiner to MPEP §2163 which recites: "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." Applicants turn the Examiner's attention to the specification and claim 1. It is unclear to the Applicants why the present invention as embraced by instant claim 1 does not comply with the written description requirement. Applicants note that "[a] description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption". MPEP §2163.04. Applicants do not believe the Examiner has offered sufficient evidence and therefore has not rebutted this presumption. The claims disclose a method for inhibiting 5-lipoxygenase in a subject comprising the administration of a compound of formula (I).

The instant specification discloses a number of examples showing an inhibition of 5-lipoxygenase and/or chemical formulae distinctly defining the variables such that a person skilled in the art would "recognize that Applicant had possession of the claimed invention." Therefore, Applicants submit that the written description requirement is satisfied and respectfully request this rejection to be withdrawn.

It would appear the Examiner's issue with working examples is in reference to claim 2, which is dependent on claim 1. It is unclear to Applicants why the Examiner has emphasized this point when the broader claim is in claim 1. The Examiner's attention is invited to the fact that working examples are not required under the written description requirement. Rather, this is a factor that is often used in enablement rejections which is not being applied here. See MPEP §2164.02 ("Working Example").

Notwithstanding the Examiner's issue with working examples, a Declaration is submitted herewith where Applicants clearly demonstrate when a drug comprising one compound of formula (I) (wherein X is CH, Y is O, n is 1, R¹ is CH₃, R² and R³ are H, R⁴ is C₂H₅, and R⁵ is H) is administered to mice, there is an effective inhibition of 5-lipoxygenase and an effective treatment of a leukotriene-related disease such as asthma. See especially Tables I – V in the Declaration. Moreover, there are numerous reports, Exhibits 1 to 11, attached herewith showing the correlation between 5-lipoxygenase and the diseases of claim 2. Therefore,

Applicants submit that it is well known in the art that such diseases can be prevented or treated by inhibiting 5-lipoxygenase as has been shown in the Declaration against asthma. Accordingly, it is believed that the written description requirement is satisfied such that a skilled artisan can practice the invention commensurate with the scope of claim 1-7 and 10.

For these reasons, it is respectfully submitted that this rejection of claims 1 – 7 and 10 under 35 USC 112, first paragraph, be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendment to the claims and remarks, it is respectfully submitted that the instant invention as defined in claims 1-7 and 10 is in full compliance with all the statutory requirements of Title 35 USC, and, therefore, it is earnestly requested that the Examiner's rejection be withdrawn and that the pending claims be passed to issue.

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Enclosures:

- Executed Declaration of Hea Young Park Choo
- Exhibit 1 (relevant to Asthma): *Curr. Med. Chem.-Anti-Inflammatory agents & Anti-allergy agents*, 2003, 2, 9-18
- Exhibit 2 (relevant to Pertussis): *British Journal of Pharmacology*, 1989, 97(4), 1265-73
- Exhibit 3 (relevant to Psoriasis): PCT WO 99/11249 (1999.03.11)
- Exhibit 4 (relevant to (Rheumatoid) Arthritis and Allergic Rhinitis): *Eur. J. Clin. Pharmacol.*, 1995, 48, 155-160
- Exhibit 5 (relevant to inflammatory bowel disease): *Advances in prostaglandin, Thromboxane, and Leukotriene Research*, 1994, 22, 113-124
- Exhibit 6 (relevant to Cystic Fibrosis, Arthritis and Psoriasis): *European Journal of Clinical Investigation*, 1995, 25, 915-919
- Exhibit 7 (relevant to Bronchitis): *Prostaglandins*, 1987, 33(5), 663-674
- Exhibit 8 (relevant to Sepsis): *Kidney International*, 2002, 61, 764-776
- Exhibit 9 (relevant to Cardiac Myoischemia): *Eur. J. Med. Chem.* 1997, 32, 687-707
- Exhibit 10 (relevant to Cardiac Anaphylaxis): *British Journal of Pharmacology*, 1988, 95, 1322-1328
- Exhibit 11 (relevant to Ischemia): *British Journal of Pharmacology*, 2001, 133, 1323-1329

CERTIFICATE OF MAILING

I hereby certify that this *Amendment and Request for Reconsideration* is being deposited with the United States Postal Service via First Class Mail addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 10, 2006.

Audrey de Souza _____ (Typed or printed name of person mailing paper or fee)

Audrey de Souza _____ (Signature of person mailing paper or fee)